The type of embolic protection does not influence the outcome in carotid artery stenting

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Objectives: **The goal of this study was to review our experience with embolic protection devices (EPDs) during carotid artery stenting (CAS). Specifically, we aimed to verify their clinical effectiveness and to compare clinical outcomes between specific devices and types of EPDs.**

Methods: **The CAS databases at four participating centers were reviewed. Adverse events were defined as death, stroke (>24 hours), or transient ischemic attack (TIA) (<24 hours). We compared the risk of procedural and 30-day events between patients treated with and without an EPD. We also compared these risks between different EPDs and between the different types of EPDs.**

Results: **A total of 3160 CAS procedures using nine EPDs were analyzed. The risk of a procedural adverse event was 0.9% in protected and 2.3% in unprotected procedures ($P = .12$). Compared with the most frequently used device (FilterWire, Boston Scientific, Natick, Mass), there was no significant difference in the risk of procedural adverse events for any of the other EPDs. There was, however, an increased risk of 30-day adverse events with the Accunet (Abbott Vascular, Redwood, Calif) filter compared with the FilterWire (relative risk [RR] 2.67, confidence interval [CI] 1.41 to 5.04, $P = .005$). Pairwise comparison of proximal occlusion balloons to filters, distal occlusion balloons to filters, and proximal to distal occlusion balloons revealed no significant difference in the risk of procedural or 30-day adverse events. There was no significant difference in risk of procedural events between eccentric and concentric filters, however, the relative risk of eccentric compared with concentric filters at 30 days was 0.59 (unadjusted, CI 0.38 to 0.92, $P = .04$). This difference was still apparent after adjustment for risk factors (RR 0.61, CI 0.39 to 0.95, $P = .06$), but not after adjustment for risk factors and stent-type [(open-cell vs closed-cell) RR 0.76, CI 0.47 to 1.22, $P = .51$].**

Conclusion: **The use of EPDs is associated with a low risk of procedural adverse events. We were unable to detect significant differences in risks of procedural adverse events between different devices or types of devices. We speculate that the observed differences seen at 30 days are largely attributable to differences in stent-type used. (J Vasc Surg 2007;46: 251-6.)**

Carotid artery stenting (CAS) and carotid endarterectomy (CEA) have been the subjects of several randomized controlled trials.[1-5] Concern over cerebral embolization of carotid plaque material during CAS led to the introduction of embolic protection devices (EPDs).[6] Although their use during CAS has not been validated in randomized trials, information from registries and observational studies support their routine use[7,8] and most consider them to be the standard of care. The three types of EPDs in current practice are the filter (concentric or eccentric), distal balloon occlusion, and proximal balloon occlusion with or without flow reversal. Balloon occlusion, whether proximal or distal, is associated with cerebral intolerance in 5% to 10% of cases.[9,10] However, their main advantage is in avoidance of crossing the lesion unprotected (proximal occlusion), or easier traversal of the lesion due to smaller crossing profiles (distal occlusion). Occlusion balloons also offer superior particle capture capability as demonstrated in clinical and experimental studies.[11] The main advantage of filters is maintenance of flow to the brain throughout the procedure, however, inability to cross very tight lesions and distal ICA spasm are potential drawbacks.

Recently, we examined the effect of device characteristics on the outcome following CAS with an emphasis on stent design.[12] The purpose of the present analysis is to review our experience with embolic protection during CAS. Specifically, we set out to verify the importance of EPD use and to compare adverse neurological event rates between specific devices and the different types of EPDs.

METHODS

The existing institutional databases of four participating centers were reviewed to select patients who underwent CAS with commercially available EPDs and stents. Only devices used in at least 25 procedures were included for analysis. All patients were screened with preoperative duplex ultrasound and magnetic resonance angiography followed by digital subtraction angiography at the time of the procedure to confirm lesions appropriate for treatment (symptomatic lesions ≥50%, asymptomatic lesions ≥80%,

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Table I. Patient demographics, risk factors, and lesion characteristics for total population of 3160 patients undergoing CAS and for all subgroups

System	*Males*	*Age > 80*	*Symptoms*	*Smoke*
TOTAL N (%)	2116 (66.7)	509 (16.1)	1309 (41.4)	1195 (37.8)
Unprotected (n = 30)	104	7	65	55
FilterWire (n = 1640)	1055	290	676	567
Spider (n = 191)	134	28	56	76
Emboshield (n = 177)	119	23	73	76
Accunet (n = 204)	154	41	84	93
Angioguard (n = 518)	338	81	234	206
Trap (n = 82)	56	13	43	31
Mo.Ma (n = 150)	109	17	49	53
NPS (n = 42)	28	6	15	23
Percusurge (n = 26)	19	3	14	15

PVD, Peripheral vascular disease.

as calculated according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria). CAS was performed with periprocedural antiplatelet therapy and anticoagulation according to the existing institutional standards of care as previously described.[13,14] All patients underwent neurological evaluation prior to the procedure, 24 hours postprocedure, and at a 30-day follow-up visit. All neurological investigations were performed by a team of independent neurologists.

Information including age, gender, presence of symptoms, and medical risk factors were recorded. The presence or absence of an EPD, the specific protection device used, and the type of protection system used were recorded and used for comparison. The specific stent used with each protection device was also recorded.

An adverse event was defined as death, stroke (persisting >24 hours), or transient ischemic attack (TIA) (neurological deficit lasting <24 hours). Event rates were recorded as procedural (occurring during the procedure only) or as 30-day (occurring during the procedure and up to 30 days after).

Statistical analysis was conducted in the statistical software package S-Plus 7.0, *P*-values below .05 (or 5%) are termed statistically significant. The primary analysis compared event rates between patients treated with and without an EPD. It also compared adverse event rates between the different protection devices used among patients treated with an EPD. The secondary analysis compared event rates between the types of protection systems (filter, proximal occlusion, or distal occlusion) and the types of filter-based protection systems (eccentric or concentric) among the patients treated with them. Comparison of event rates between different groups was based on (a two-sided) Pearson's χ^2 test with Yates correction whenever appropriate (ie, whenever the expected cell counts exceeded five in at least 80% of all cells). Fisher exact test was used in all other cases. Risk ratios (ie, relative risks) and small-sample adjusted 95% confidence intervals were used to quantify the comparison of complication event risks between different groups. Due to the low number of events, no risk ratios were calculated for TIA, stroke, and death rates separately. Adjustment for risk factors was done via exponential risk models, excluding risk factors one by one if nonsignificant at the 5% significance level. *P*-values for the secondary analysis were adjusted for multiple testing errors through Bonferroni correction.

RESULTS

A total of 3281 CAS procedures were scheduled between 1997 and 2006. Of these, 11 were treated with CEA instead due to unsuccessful common carotid engagement or EPD delivery or deployment. Thirty-one of these were treated with angioplasty alone, 37 were treated with either a stent or EPD that was never commercially available, and 42 were treated using devices that were used in <25 procedures (range 1 to 13). This left 3160 CAS procedures and nine EPDs available for analysis.

Patient and lesion characteristics are listed in Table I. There was significant variability in the distribution of smoking ($P = .01$), presence of other peripheral vascular disease ($P = .005$), hypercholesterolemia ($P = .001$), and lesion calcification ($P = .005$) between protection systems. Of the 3160 CAS procedures, 3030 (95.9%) were performed with protection and 130 (4.1%) without. In all, there were 29 (0.9%) procedural and 90 (2.8%) 30-day events. There were fewer procedural events when an EPD was used, however this did not reach statistical significance (Table II).

Of the 3030 protected procedures, eccentric filters (FilterWire, Boston Scientific Corp, Natick, Mass; Spider, ev3, Plymouth, Minn) were used in 1831 (60.4%), concentric filters (Emboshield, Abbott Vascular, Redwood City, Calif; Angioguard, Cordis, Miami Lakes, Fla; Trap, ev3, Plymouth, Minn; Accunet, Abbott Vascular, Redwood City, Calif) in 981 (32.4%), proximal occlusion (NPS, W. L. Gore & Associates, Flagstaff, Ariz; Mo.Ma, Invatec, Roncadelle, Italy) in 192 (6.3%) and distal occlusion (Percusurge, Medtronic, Santa Rosa, Calif) in 26 (0.9%) cases. Closed cell stents in which all stent-struts are interconnected (Carotid Wallstent, Boston Scientific Corp, Natick, Mass; X-act, Abbott Vascular, Redwood City, Calif; Nextent, Endotex, Cupertino, Calif) were used in 2120 (70.0%) cases and open cell stents in which not all stent-

Table I. Continued.

Hypertension	*Diabetes*	*Other PVD*	*Hypercholesterolemia*	*Calcification*	*Restenosis after surgery*
2278 (72.1)	823 (26.0)	1432 (45.3)	1990 (63.0)	777 (24.5)	204 (6.5)
100	23	68	93	3	3
1179	450	709	999	540	127
133	52	102	114	41	9
131	48	87	121	10	9
156	54	115	148	54	10
374	119	224	328	101	32
57	26	36	57	4	9
106	38	75	95	14	4
24	6	3	16	9	0
18	7	13	19	1	1

Table II. Procedural and 30-day adverse events comparing patients treated with and without a protection system

Event-time	*Frequency - N (%)*	*RR*	*95% CI*	P
30-days				
Protected (n = 3030)	87 (2.9) [68 TIA; 13 stroke; 7 death]			
Unprotected (n = 130)	3 (2.3) [3 TIA]	1.25	0.40-3.88	1.00
Procedural				
Protected (n = 3030)	26 (0.9) [20 TIA; 6 stroke]			
Unprotected (n = 130)	3 (2.3) [3 TIA]	0.38	0.12-1.24	.12

RR, Relative risk compared with protected stenting; *CI,* confidence interval; *TIA,* transient ischemic attack.

Table III. Proportion of closed-cell stents used in conjunction with the different types of protection

Protection-type	*Closed-cell stents used - N (%)*
Unprotected (n = 130)	114 (87.7)
Concentric filter* (n = 981)	488 (49.7)
Eccentric filter† (n = 1831)	1467 (80.1)
Proximal occlusion‡ (n = 192)	141 (73.4)
Distal occlusion§ (n = 26)	24 (92.3)

*Emboshield, Angioguard, Trap, Accunet.
†FilterWire, Spider.
‡NPS, Mo.Ma.
§Percusurge.

struts are interconnected (Precise, Cordis, Miami Lakes, Fla; Exponent, Medtronic, Santa Rosa, Calif; Protégé, ev3, Plymouth, Minn; Acculink, Abbott Vascular, Redwood City, Calif) were used in 910 (30%) cases. Table III describes the proportion of closed cell stents used in conjunction with each protection type.

The procedural and 30-day events are expressed in absolute risks and risks relative to the most commonly used EPD in this study (FilterWire, Boston Scientific) in Tables IV and V. This comparison is not adjusted for risk factors due to low sample size for some of the devices. When comparing individual EPDs to the FilterWire, a statistically significant increased 30-day event rate was found for the Accunet (Abbott Vascular) concentric filter. There was also an increased 30-day and procedural event rate observed for the Percusurge (Medtronic) distal occlusion balloon, although not statistically significant. Two patients in this group had events. One of them was a procedural event at which time visible leaking of the balloon was noted. The other was a late event of unknown cause.

Risk ratios of procedural and 30-day events comparing the different types of protection systems before and after adjustment for risk factors are listed in Table VI. A statistically significant difference was found in favor of eccentric filters compared with concentric filters at 30 days only ($P = .04$). After adjustment for risk factors, a trend remained in favor of eccentric filters ($P = .06$). After adjustment for stent-type (closed cell vs open cell) after-which this difference was no longer apparent ($P = .51$).

DISCUSSION

In the present retrospective analysis, we were unable to show a statistically significant clinical benefit for the use of EPDs despite 60% fewer procedural events in protected procedures. This may be due to small sample size in the unprotected group and low event rates in either group. Interestingly, each of the three 30-day events in the unprotected group represented events that occurred during the procedure itself. There also exists potential selection bias, as the procedures performed without neuroprotection were done before EPDs were widely available and so lesions with higher risk for embolization may have been deferred to CEA or medical management.

Diffusion-weighted imaging has recently been used to demonstrate a reduction in embolic events with the use of EPDs during CAS.[15] Although there was no significant

Table IV. Procedural adverse events for nine EPD systems

System	*Frequency - N (%)*	*RR*	*95% CI*	P
FilterWire (n = 1640)	16 (1.0) [11 TIA; 5 stroke]			
Spider (n = 191)	0 (0)	0.00	0.00-∞	.40
Emboshield (n = 177)	0 (0)	0.00	0.00-∞	.40
Accunet (n = 204)	1 (0.49) [1 TIA]	0.50	0.07-3.75	1.00
Angioguard (n = 518)	5 (0.97) [5 TIA]	0.99	0.36-2.68	1.00
Trap (n = 82)	1 (1.22) [1 TIA]	1.24	0.17-9.20	.57
Mo.Ma (n = 150)	1 (0.67) [1 TIA]	0.68	0.09-5.09	1.00
NPS (n = 42)	1 (2.38) [1 stroke]	2.39	0.32-17.57	.35
Percusurge (n = 26)	1 (3.85) [1 TIA]	3.80	0.52-27.59	.24

RR, Relative risk compared with FilterWire (Boston Scientific); *CI,* confidence interval; *TIA,* transient ischemic attack.

Table V. Thirty-day adverse events for nine EPD systems

System	*Frequency - N (%)*	*RR*	*95% CI*	P
FilterWire (n = 1640)	36 (2.2) [23 TIA; 9 stroke; 4 death]			
Spider (n = 191)	4 (2.1) [4 TIA]	0.95	0.34-2.64	1.00
Emboshield (n = 177)	6 (3.39) [5 TIA; 1 death]	1.54	0.66-3.60	.29
Accunet (n = 204)	12 (5.88) [11 TIA; 1 stroke]	2.67	1.41-5.04	.005
Angioguard (n = 518)	17 (3.28) [14TIA; 2 stroke; 1 death]	1.49	0.85-2.64	.19
Trap (n = 82)	2 (2.44) [2 TIA]	1.10	0.27-4.48	.70
Mo.Ma (n = 150)	6 (4.0) [6 TIA]	1.81	0.78-4.23	.16
NPS (n = 42)	2 (4.76) [1 stroke; 1 death]	2.12	0.53-8.52	.24
Percusurge (n = 26)	2 (7.69) [2 TIA]	3.38	0.86-13.29	.12

RR, Relative risk compared with FilterWire (Boston Scientific); *CI,* confidence interval; *TIA,* transient ischemic attack.

Table VI. Comparison between different types of protection systems, before and after adjustment for risk factors and stent-type

	Procedural events			*30-day events*		
Comparison	*RR*	*95% CI*	P	*RR*	*95% CI*	P
Proximal occlusion vs filter						
Unadjusted	1.28	0.30-5.37	1.00	1.52	0.75-3.13	1.00
Adjusted for RF	1.34	0.22-4.54	1.00	1.57	0.70-3.06	1.00
Adjusted for RF, ST	1.34	0.22-4.54	1.00	1.59	0.71-3.10	1.00
Distal occlusion vs filter						
Unadjusted	4.56	0.64-32.52	1.00	2.72	0.71-10.51	.96
Adjusted for RF	4.34	0.24-20.60	1.00	2.69	0.44-8.53	1.00
Adjusted for RF, ST	4.32	0.24-20.90	1.00	3.38	0.55-10.87	.54
Distal vs proximal occlusion						
Unadjusted	3.57	0.34-38.05	1.00	1.79	0.40-7.96	1.00
Adjusted for RF	3.57	0.34-38.05	1.00	1.79	0.40-7.96	1.00
Adjusted for RF, ST	3.57	0.34-38.05	1.00	1.79	0.40-7.96	1.00
Eccentric vs concentric filter						
Unadjusted	1.25	0.52-3.03	1.00	0.59	0.38-0.92	0.04
Adjusted for RF	1.31	0.56-3.41	1.00	0.61	0.39-0.95	0.06
Adjusted for RF, ST	1.33	0.55-3.57	1.00	0.76	0.47-1.22	0.51

RF, Risk factors; *ST,* Stent-type (open-cell or closed-cell); *RR,* relative risk; *CI,* confidence interval.

difference in clinical outcome between the treatment and control groups in this study, the authors noted a correlation between the number of new cerebral lesions and stroke. Conversely, another prospective study comparing filter-protected with unprotected patients, saw significantly more micro-emboli on transcranial Doppler ultrasound in the filter group.[16] Again, there was no statistical difference in clinical outcome between groups. In the latter study, selection bias could have played a role, favoring higher-risk lesions in the filter group. Both these studies, like the present one, suffered from small sample sizes relative to event rates. In order to resolve this issue, two large reviews pooled data from multiple reports and registries and showed significantly fewer neurological events after the introduction of EPDs.[8,17] Still, while EPDs may be beneficial, concurrent advancements in stent and guidewire

technology, and in antiplatelet and statin agents have also potentially played a role. Even so, sufficient data is available to state that EPDs are safe and feasible, and so continued use is likely justified until further information from randomized trials is available to clarify their role.

One of the main difficulties in determining equivalence or superiority of any particular EPD is caused by the presence of confounders. In the present study, we adjusted for patient risk factors when evaluating the different types of EPDs. We were unable to do the same when analyzing the specific devices due to lower sample sizes. It is unlikely, however, that this would have had a great impact, given that risk factor adjustment did not have a major effect on our secondary analysis. A more significant confounder results from the frequent device pairing that occurs (ie, a given EPD is usually sold with a corresponding stent from the same manufacturer) due to product marketing. With recent evidence suggesting an impact of stent-design on CAS outcomes[18] this becomes even more important.

For example, significantly more adverse events were seen at 30 days, but not at the time of the procedure, for the Accunet (Abbott Vascular) filter compared with the FilterWire (Boston Scientific). Open cell stents were used with this device in over 65% of cases, the predominant one being Acculink (Abbott Vascular) stent which has the highest free cell area of the stents used in this study. In the light of our previous report,[18] it is due to the larger free cell area, which leads to a greater risk of plaque debris embolization through the struts of the stent. This showed to significantly increase the risk on 30-day adverse events, and it is therefore that we believe this difference seen at 30 days was primarily the effect of the selection of the stent-type with the large free cell area.

We did not initially adjust for stent-type in comparing the specific EPDs, because in most cases it is not practical to "unpair" the devices, and so the information provided would not be clinically relevant for most operators. However, observed differences at 30 days but not at the time of the procedure needs explanation. It is possible that vessel wall injury caused by the EPD can result in late events. An animal model demonstrated a correlation between debris capture and vessel wall injury from filter placement[19] during the procedure. It is possible that this can translate to late embolic events from wall debris or thrombus. Alternatively, we thought it more likely that the 30-day differences we observed between eccentric and concentric filters and probably also for the Accunet (Abbott Vascular) filter were the result of the different stent-designs used. To confirm this, we performed an analysis on the comparison between EPD types adjusting for stent type (open cell vs closed cell). Following adjustment, the advantage of eccentric over concentric filters at 30 days disappeared. Some of this was the result of adjusting for risk factors, however, the trend that still existed disappeared after adjustment for stent-type. It appears that the observed benefit was largely due to the use of closed cell stents.

In the present analysis both filter types performed well at the time of the procedure. In comparison, the procedural event rate observed with the only distal occlusion device used in this study was quite high (3.70%), although not statistically significant. Device malfunction was possibly the cause of one of these events (balloon leakage). The NPS (Gore) device also performed less well than the other devices (2.38% procedural event rate). It is possible, given the lower sample sizes for these devices in our study that a certain learning curve exists, as noted by others.[20,21]

In their recent publication, Zahn et al found that in-hospital combined event rates were comparable whether filters or distal occlusive devices were used during CAS.[22] This was despite there being double the proportion of lesions requiring predilatation in the distal occlusion group. This emphasizes the potential advantage of these devices given their slimmer crossing-profile. This may be more relevant than the higher capture counts seen with occlusion devices[11] as many small particulate debris appear to be clinically silent.[15] Another review had similar findings, however, they noted a 10% rate of cerebral intolerance to balloon occlusion.[10] In order to avoid this, they stated a preference for filter devices except in cases of severe critical stenoses. Such a lesion-specific approach to device selection seems appropriate unless a clear advantage of one device over the other is established.

Although the results of this subanalysis fail to prove earlier published potential theoretical advantages and disadvantages of different EPD in specific indications.[23] It is claimed that different geometries and working principles of EPDs on the market provide each with unique functional properties and that the individual characteristics of each device may make it an attractive choice in one circumstance, but render it less desirable in other situations. In-depth investigation is required to confirm this thesis.

The present study is limited due to its retrospective nature. Potential selection biases may have occurred in selecting the unprotected CAS patients as discussed above. It is also possible that selection bias can occur when choosing a particular EPD. Although tailoring the choice of device to the lesion is likely appropriate, this was not done in the present study. This stems from the fact that the procedures were almost all performed in the context of a CAS training program or trial sponsored by a particular company. Therefore, the date of the intervention was the predominant factor in determining which device was used. Device-specific complications such as arterial damage, spasm, and cerebral intolerance were not recorded in this review. It would have been interesting to note if these events impacted clinical outcome, although we suspect not given the observations of others.[20] Similarly, patients did not undergo routine CT or MRI examinations or transcranial Doppler monitoring during the procedure, so an objective measure of the degree of embolization occurring with correlation to clinical outcome could not be made. Due to the low number of events, it was only possible to investigate risk ratios for the total procedural and 30-day adverse event rates between the different modalities.

CONCLUSION

The use of EPDs is associated with a low procedural complication rate. There was no significant difference in procedural adverse neurological events observed for any of the EPDs or types of EPDs. The differences seen in 30-day events observed are largely attributable to the difference in stent-type (closed vs open cell) used in conjunction with the EPD.

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AUTHOR CONTRIBUTIONS

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Analysis and interpretation: MB, VI
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Writing the article: MB, VI
Critical revision of the article: KD, PP, GD
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REFERENCES

1. Ringleb PA, Allenberg J, Bruckmann H, Eckstein HH, Fraedrich G, Hartmann M, et al; SPACE Collaborative Group. 30-day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomized non-inferiority trial. Lancet 2006;368:1239-47.
2. Mas JL, Chatellier G, Beyssen B, Branchereau A, Moulin T, Becquemin JP, et al; EVA-3S Investigators. Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. N Engl J Med 2006; 355:1660-71.
3. Yadav JS, Wholey MH, Kuntz RE, Fayad P, Katzen BT, Mishkel GJ, et al; Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators. Protected carotid-artery stenting versus endarterectomy in high-risk patients. N Engl J Med 2004;351:1493-501.
4. Hobson RW 2nd, Howard VJ, Roubin GS, Brott TG, Ferguson RD, Popma JJ, et al; CREST Investigators. Carotid artery stenting is associated with increased complications in octogenarians: 30-day stroke and death rates in the CREST lead-in phase. J Vasc Surg 2004;40:1106-11.
5. CAVATAS Investigators. Endovascular versus surgical treatment in patients with carotid stenosis in the Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS): a randomized trial. Lancet 2001;357:1729-37.
6. Theron J, Courtheoux P, Alachkar F, Bouvard G, Maiwa D. New triple coaxial catheter system for carotid angioplasty with cerebral protection. AJNR Am J Neuroradiol 1990;11:869-74.
7. Zahn R, Mark B, Niedermaier N, Zeymer U, Limbourg P, Ischinger T. Embolic protection devices for carotid artery stenting: better results than stenting without protection? Eur Heart J 2004;25:1550-8.
8. Wholey MH, Al-Mubarek N, Wholey MH. Updated review of the global carotid artery stent registry. Catheter Cardiovasc Interv 2003;60: 259-66.
9. Whitlow PL, Lylyk P, Londero H, Mendiz OA, Mathias K, Jaeger H, et al. Carotid artery stenting protected with an emboli containment system. Stroke 2002;33:1308-14.
10. Powell RJ, Alessi C, Nolan B, Rzucidlo E, Fillinger M, Walsh D, et al. Comparison of embolization protection device-specific technical difficulties during carotid artery stenting. J Vasc Surg 2006;44:56-61.
11. Müller-Hülsbeck S, Jahnke T, Liess C. Comparison of various cerebral protection devices used for carotid artery stent placement: an in vitro experiment. J Vasc Interv Radiol 2003;14:613-20.
12. Bosiers M, de Donato G, Deloose K, Verbist J, Peeters P, Castriota F, et al. Does free cell area influence the outcome in carotid artery stenting? Eur J Vasc Endovasc Surg 2007;33:135-41.
13. Sprouse LR 2nd, Peeters P, Bosiers M. The capture of visible debris by distal cerebral protection filters during carotid artery stenting: is it predictable? J Vasc Surg 2005;41:950-5.
14. Bosiers M, Peeters P, Verbist J, Schroe H, Deloose K, Lauwers G, et al. Belgian experience with FilterWire EX in the prevention of embolic events during carotid stenting. J Endovasc Ther 2003;10:695-701.
15. Kastrup A, Nägele T, Gröschel K, Schmidt F, Vogler E, Schulz J, et al. Incidence of new brain lesions after carotid stenting with and without cerebral protection. Stroke 2006;37:2312.
16. Vos JA, van den Berg JC, Ernst SM, Suttorp MJ, Overtoom TT, Mauser HW, et al. Carotid angioplasty and stent placement: comparison of transcranial Doppler US data and clinical outcome with and without filtering cerebral protection devices in 509 patients. Radiology 2005; 234:493-9.
17. Kastrup A, Groschel K, Krapf H, Brehm BR, Dichgans J, Schulz JB. Early outcome of carotid angioplasty and stenting with and without cerebral protection devices: a systematic review of the literature. Stroke 2003;34:813-9.
18. Hart JP, Peeters P, Verbist J, Deloose K, Bosiers M. Do device characteristics impact outcome in carotid artery stenting? J Vasc Surg 2006; 44:725-30.
19. Müller-Hülsbeck S, Stolzmann P, Liess C, Hedderich J, Paulsen F, Jahnke T, et al. Vessel wall damage caused by cerebral protection devices: ex vivo evaluation in porcine carotid arteries. Radiology 2005; 235:454-60.
20. Cremonesi A, Manetti R, Setacci F, Setacci C, Castriota F. Protected carotid stenting: clinical advantages and complications of embolic protection devices in 442 consecutive patients. Stroke 2003;34:1936-41.
21. Verzini F, Cao P, De Rango P, Parlani G, Maselli A, Romano L, et al. Appropriateness of learning curve for carotid artery stenting: an analysis of periprocedural complications. J Vasc Surg 2006;44:1205-11.
22. Zahn R, Ischinger T, Mark B, Gass S, Zeymer U, Schmalz W, et al. Embolic protection devices for carotid artery stenting: is there a difference between filter and distal occlusive devices? J Am Coll Cardiol 2005;45:1769-74.
23. Bosiers M, Peeters P, Deloose K, Verbist J. Comparison of cerebral protection devices for carotid artery stenting. Schneider et al: carotid interventions (5932-X) 2004;13:173-86.

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